PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61F 2/44, 2/46, A61B 17/58, 17/02

A2

(11) International Publication Number: **WO 96/40016**

(43) International Publication Date: 19 December 1996 (19.12.96)

(21) International Application Number: PCT/US96/09114

(22) International Filing Date: 6 June 1996 (06.06.96)

(30) Priority Data:

08/475,211	7 June 1995 (07.06.95)	US
08/482,974	7 June 1995 (07.06.95)	US

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

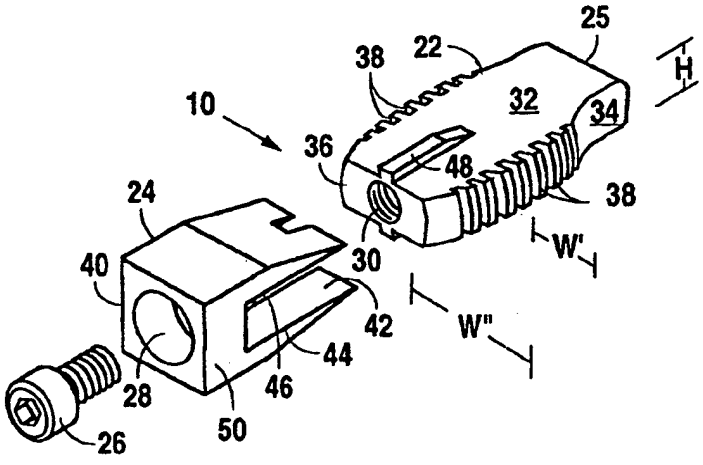
(71)(72) Applicant and Inventor: PISHARODI, Madhavan [US/US]; 942 Wild Rose Lane, Brownsville, TX 78520 (US).

(74) Agent: WISNER, Mark, R.; Sroufe, Payne & Lundeen, L.L.P., Suite 1230, 1700 West Loop South, Houston, TX 77027-3008 (US).

(54) Title: INTERVERTEBRAL DISK STABILIZER AND INSTRUMENT FOR REDUCTION OF SPONDYLOLISTHESIS

(57) Abstract

A middle expanded, removable disk implant (22) with substantially rectangular cross-sectional shape with a minimal height (H) and a width (W) greater than the height which is detachably mounted to an applicator (52) for insertion into the anatomical region between two adjacent vertebrae (16, 18) from which a portion of the intervertebral disk has been removed. The implant is positioned by anterior-posterior movement in the disk space to the position in which both the expanded middle portion and the smaller diameter end (25, 36) portions of the implant engage the bodies (12, 14) of the adjacent vertebrae and then rotated to bring the sides (34) of the implant defining the height of the implant into engagement with the bodies of the adjacent vertebrae. A lock (24) is then secured to the implant to prevent further rotation thereof. In the event the adjacent vertebrae need to be aligned before fusion, an elongate implant (112) is provided which is split longitudinally into side-by-side members (113, 114) movable relative to each other and which is inserted into the disk space between two misaligned vertebrae (133, 137). The members are provided with teeth (138) for engaging the adjacent vertebrae and the implant formed by the two side-by-side members is rectangularly-shaped in cross section, the height (H_6) of the rectangularly-shaped cross section being less than the width (W_6) so that the implant can be inserted between the adjacent vertebrae with the lesser, height dimension oriented in the same direction as the axis of the spinal column and the larger width dimension at approximately a right angle to that axis. One member is then moved relative to the other from the first side-by-side position along the longitudinal axis of the implant to a second position in which the members are aligned with the respective, adjacent, misaligned vertebrae and the implant is rotated 90° to engage the teeth to the bodies of the adjacent vertebrae. The two members are then brought back into the first side-by-side position to draw the vertebrae into alignment and the implant is rotated approximately 90° to disengage the teeth from the vertebrae for removal from the disk space.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

INTERVERTEBRAL DISK STABILIZER AND INSTRUMENT FOR REDUCTION OF SPONDYLOLISTHESIS

The present invention relates to an intervertebral implant and a method of stabilizing adjacent vertebrae. More specifically, the present invention relates to rectangularly-shaped disk implants which are expanded in the middle portion used for spinal fusion. If necessary in treating the patient, the present invention also contemplates reduction of spondylolisthesis, e.g., alignment of the vertebrae comprising the spinal column. In this second aspect, the present invention relates to apparatus which is inserted into the space between adjacent, misaligned vertebrae, engages the bodies of the adjacent vertebrae, and pulls the vertebrae back into alignment.

Disorders of the spinal column, especially in the neck or lumbar region, continue to be a challenging field of medicine. Classical treatments for conditions involving subluxation of one vertebrae upon another, resulting in misalignment of the spinal column, use screws which extend through a plate and which are tightened to draw the misaligned vertebrae back into alignment. However, such conditions often involve damage to the intervertebral disk, e.g., rupture or herniation, which may result in compression of a nerve root. If the herniation is large, compression may be bilateral. This condition is usually not corrected by re-aligning the vertebrae with a plate and screws such that surgical removal of the disk followed by fusion is often indicated after reduction of spondylolisthesis. The classical treatment for a ruptured disk is diskectomy, i.e., removal of the disk from between the vertebrae. In this process. all or a portion of the intervertebral disk is removed, leaving a defect which bothers the patient throughout the rest of their life. An additional procedure is to replace the disk space with a bone graft, usually bone chips cut from the patient's iliac crest, bringing about fusion of the vertebrae above and below the disk and eliminating the space between the vertebrae.

However, diskectomy with fusion is not ideal because the replaced bone does not have the function of the cartilaginous tissue of the disk, i.e. no cushioning effect, and has several complications. First, conventional bone plugs used to pack the disk space do not conform to the space of the disk because the disk space is wider in the middle and narrower at its anterior and posterior ends. For this reason, currently available bone plugs have only four contact points, i.e. at the front and back of the

disk space. Secondly, access to the disk is from the side of the dorsal spine of the adjacent vertebrae, leaving a space that is "off-center" relative to the bodies of the adjacent vertebrae such that the stability of the implant is even more problematical than might be apparent from the limited contact resulting from the shape of the intervertebral space. Another complication is the possibility of infection or other conditions which may require the removal of the implant. Also, if the bone pieces do not fuse, they may eventually extrude out of the disk space, causing pressure on the nerve roots.

Various prosthetic disk plugs, or implants, are disclosed in the art, but all are characterized by limitations of not conforming to the shape of the disk space, lack of stability when inserted off-center, difficulty in precise positioning, inability to be removed, or other disadvantages. For instance, U.S. Patent No. 4,863,476 (and its European counterpart, EP-A-0260044) describes an elongated body divided longitudinally into two portions having a cam device for increasing the space between the two body portions once inserted into the disk space. However, that device is generally cylindrical in shape such that the only contact points are at the front and back of the disk space, creating increased likelihood of instability. The art also discloses intervertebral disk prostheses (e.g., U.S. Patent Nos. 3,867,728, 4.309.777, 4.863,477 and 4,932,969 and French Patent Application No. 8816184) which may have more general contact with the adjacent disks, but which are not intended for use in fusion of the disks. The art also includes spinal joint prostheses such as is described in U.S. Patent No. 4,759,769, which is again not indicated for use when fusion is the preferred surgical intervention.

There is, therefore, a need for treatment of conditions involving misalignment and fusion of the spinal column, as specifically for a device capable of aligning and stabilizing the vertebrae adjacent an intervertebral disk for use in spinal fusion. These needs are met in the present invention by providing a vertebral disk stabilizer comprising an elongate implant having first, second, third and fourth sides providing the implant with a substantially rectangular cross-sectional shape of minimal height defined by the first and second sides and maximal width defined by the third and fourth sides, the third and fourth sides being arched from one end of the implant to the other to provide the portion intermediate the ends with a width larger than the width of the implant at the ends thereof. A lock having a bearing surface formed thereon is detachably mounted to one end of the implant to prevent rotation of the

lock relative to the implant with the bearing surface oriented at approximately 90° to the height of the implant.

Also provided is a method of stabilizing two adjacent vertebrae after removing a portion of the intervertebral disk from therebetween to form a disk space comprising the steps of inserting a substantially rectangularly-shaped, elongate implant having a width greater than its height into the disk space with the implant oriented so that the top and bottom thereof engage the bodies of the adjacent vertebrae. rotating the implant approximately 90° in the disk space to contact the bodies of the adjacent vertebrae with the sides of the implant, and thereafter preventing rotation of the implant relative to the vertebrae.

Also provided is an apparatus for aligning adjacent vertebrae comprising an elongate handle having a longitudinal bore therethrough, an implant comprised of first and second side-by-side members, the first member being integrally mounted to the handle. and means formed on the implant for selectively engaging adjacent vertebrae to prevent relative movement between the respective first and second members and the adjacent vertebrae. A mandrel is positioned in the bore in the handle and is connected to the second member for moving the second member relative to the first member in the direction of the longitudinal axis of the handle. To facilitate precise movement of the second member relative to the first, and to confer the mechanical advantage which may be required to draw the adjacent vertebrae into alignment. the mandrel is preferably threaded and the bore in the handle is provided with a matching set of threads such that rotation of the mandrel causes movement of the second member along the longitudinal axis of the handle.

Also provided is a method of aligning adjacent vertebrae after removing a portion of the intervertebral disk from therebetween to form a disk space comprising the steps of inserting an elongate implant comprised of first and second side-by-side members having means formed thereon for selectively engaging the vertebrae adjacent the disk space into the disk space and moving the second member relative to the first member until the first and second members are approximately aligned with the adjacent vertebrae. The implant is rotated by approximately 90° to cause the vertebrae engaging means to engage the vertebrae and the second member is then moved relative to the first member to align the vertebrae to which it is engaged with the vertebrae to which the first member is engaged.

Referring now to the drawings, Figure 1 is a lateral view of a portion of a human spinal column having the vertebral disk stabilizer of the present invention

inserted therein and having a portion of the bodies of the vertebrae adjacent the implant shown cut away and/or in shadow lines to show the engagement of the vertebral bodies by the vertebral disk stabilizer.

Figure 2 is an exploded, perspective view of the vertebral disk stabilizer of Fig. 1.

Figure 3 is a top plan view of the implant of Fig. 1 having a handle mounted thereto in place of the lock shown in Fig. 2.

Figure 4 is an exploded, perspective view of a second preferred embodiment of the vertebral disk stabilizer of the present invention.

Figure 5 is a longitudinal, partial sectional view of a preferred embodiment of an apparatus for correcting misalignment of two adjacent vertebrae constructed in acoordance with the present invention.

Figure 6 is an end view of the apparatus of Fig. 5.

Figure 7 is a view similar to that of Fig. 5 but with the mandrel removed therefrom.

Figure 8 is an end view of the apparatus of Fig. 5.

Figure 9 is a side, elevational view of the mandrel of the mandrel after removal from the apparatus of Fig. 5.

Figure 10 is an end view of the mandrel of Fig. 5.

Figure 11 is a partially schematic, lateral view of a portion of the lumbar spine showing the use of the apparatus of Fig. 5 to align the fourth and fifth lumbar vertebrae.

Figure 12 is a top, plan view of an alternative embodiment of the apparatus of Fig. 5 showing the two halves of the body in their first, side-by-side position.

Figure 13 is a top, plan view of the apparatus of Fig. 12 showing the two halves of the body in the second position.

In more detail, a disk stabilizer constructed in accordance with the teachings of the present invention is shown implanted in a human spinal column in Fig. 1. The vertebral disk stabilizer, indicated generally at reference numeral 10, is implanted between the bodies 12 and 14 of two adjacent vertebrae 16 and 18, respectively, in the disk space (not numbered) from which a portion of the intervertebral disk 20 is removed, i.e. by simple diskectomy and small laminotomy.

Referring now also to Fig. 2, the vertebral disk stabilizer 10 is comprised of an elongate implant 22. lock 24, and means for detachably mounting the lock 24 to one end 25 of the implant 22. In the presently preferred embodiment shown, the

mounting means takes the form of a bolt 26 passing through a bore 28 in lock 24, the threads of bolt 26 engaging complementary threads in the walls of the bore 30 in the end 25 of implant 22.

In more detail, implant 22 is comprised of first and second sides 32 and third and fourth sides 34 defining a substantially rectangularly-shaped cross-section. The height H of the rectangularly shaped cross-section is defined by first and second sides 32 and the width W is defined by the third and fourth sides 34 and, as is apparent by comparison of H and W, the height of H of implant 22 is less than the width W. As will be explained below, H is minimized to facilitate insertion of the second end 36 into. and positioning of implant 22 in, the disk space from which a portion of the intervertebral disk 20 was removed and W is maximized to provide the desired stabilization to adjacent vertebrae 16 and 18. Third and fourth sides 34 are arched from one end of implant 22 to the other to provide the portion of implant 22 intermediate the ends 25 and 36 with a width W' which is larger than the width W" at the ends 25 and 36. Because the sides 32 of implant 22 are substantially flat and the sides 34 are arched from one end 25 to the other end 36, implant 22 is described as being a biplanar, bi-convex implant. The bi-convex sides 34 of implant 22 are provided with a plurality of teeth 38 for biting into the adjacent vertebrae 16 and 18 as will be explained in more detail below. The end 36 of implant 22 is formed in a blunt, or rounded shape to reduce the likelihood of injury to the nerves of the spinal cord during insertion into the disk space.

In the preferred embodiment shown, lock 24 is substantially square when viewed from the end 40 along the axis of the bore 28 therethrough and U-shaped when viewed from the side. The inside surfaces 42 of the arms 44 of the U-shaped lock 24 are flat for contacting the first and second sides 32 of implant 22 to prevent rotation of lock 24 relative to implant 22 when lock 24 is mounted to implant 22 and secured thereto by bolt 26. The surfaces 42 are provided with a slot 46 for receiving a complementary-shaped key 48 to facilitate assembly of lock 24 to implant 22. The slot 46 may also be located on the implant 22 and the key 48 may be located on the lock 24 without any difference in the function of those component parts. The bore 28 in lock 24 is aligned with the bore 30 in implant 22.

The sides of the square end 40 of lock 24 provide surfaces 50 for bearing against the bodies 12 and 14 of adjacent vertebrae 16 and 18 as also explained in more detail below. It will be recognized by those skilled in the art who have the benefit of this disclosure that the bearing surfaces 50 need not be flat and that the end

40 of lock 24 need not be square. Other shapes and configurations may be utilized as needed to insure that movement of lock 24 is limited by the bodies of the adjacent vertebrae 16 and 18. The purpose of the bi-planar, middle expanded, bi-convex implant 22 is to enable insertion of the implant 22 into the disk space and turning by approximately 90° to increase the disk height and stabilize the disk space. The purpose of lock 24 is to lock implant 22 against instability when in the vertical position so as to maintain the disk height thereafter.

Referring now to Fig. 3, there is shown an applicator 52 mounted to the end 25 of implant 22. In the embodiment shown, applicator 52 is mounted to implant 22 by screwing the threaded end 54 thereof into the threaded bore 30 in implant 22. When the end 54 of applicator 52 is screwed all the way into the bore 30, so as to prevent relative movement therebetween, implant 22 is inserted into the disk space and rotated therein using applicator 52 as explained below. Applicator 52 is detached from implant 22 by rotating in the opposite direction while rotation of implant 22 is restrained.

The use of the stabilizer 10 of the present invention in, for instance, a method of lumbar intervertebral disk stabilization, or "LIDS," is illustrated in Fig. 1. Surgery is performed as in a simple diskectomy and the intervertebral disk 20 is exposed through a small laminotomy. The disk material is removed and any nerve root compression is corrected. The posterior longitudinal ligament (not shown) and disk cartilage are removed until the surface of the bodies 12 and 14 of adjacent vertebrae 16 and 18. respectively, are exposed above and below the disk space.

Using spreaders such as those disclosed in International Application No. PCT/US95/00347, the vertebrae 16 and 18 are distracted to open the disk space, and once the desired "spread" is achieved, the middle portion of the disk space is packed with cancellous bone chips (not shown). Because the posterior longitudinal iigament is left intact to the opposite side and to the center of the disk space, the bone chips are held in place in the disk space.

An implant 22 having a height H and width W selected to fit the disk space is then mounted on applicator 52 by screwing on to the threaded end 54. The appropriately-sized implant 22 is then inserted into the disk space using the applicator 52 with the implant 22 oriented so that the top and bottom thereof, i.e., the first and second sides 32, engage the bodies 12 and 14 of adjacent vertebrae 16 and 18. respectively. Using the applicator 52, implant 22 is then moved further into (or back out of) the disk space in an anterior-posterior direction so as to enable the

implant 22 to be positioned in the disk space at a position in which the expanded, middle portion and the smaller width ends 25 and 36 of the third and fourth sides 34 of implant 22 contact the respective lower and upper surfaces of the bodies 12 and 14 of the adjacent vertebrae 16 and 18 when rotated by approximately 90° using the applicator 52. To facilitate this rotation, the corners of the implant 22 between the first and second surfaces 32 and the third and fourth surfaces 34 are rounded as shown at 35, the rounded corners 35 effectively acting as planes, or ramps, to lever the adjacent vertebrae 16 and 18 apart during rotation. The respective lower and upper surfaces of the vertebral bodies 12 and 14 are slightly concave such that the larger width middle portion W" of implant 22 allows the implant 22 to engage substantially more of the respective surfaces of the vertebral bodies 12 and 14 than conventional prosthetic devices, thereby providing increased stability to the fusion once further rotation of implant 22 in the disk space is prevented as described below.

Once the implant 22 is positioned in the disk space, the applicator 52 is detached by unscrewing and backed out of the incision in the patient. Lock 24 is then inserted through that same incision and, using the slot 46 and key 48, the bore 28 in lock 24 and bore 30 in implant 22 are aligned and the bolt 26 is inserted and tightened to secure lock 24 to the implant 22. Securing the lock 24 to implant 22 in this manner prevents relative rotation between lock 24 and implant 22 and the bearing surfaces 50 of lock 24 bear against the bodies 12 and 14 of the adjacent vertebrae 16 and 18 to prevent rotation of the lock 24 relative to the adjacent vertebrae 16 and 18 against which the bearing surfaces 50 bear. The bearing surfaces 50 bear against the cortical end plates of the respective vertebral bodies 12 and 14, which are comprised of non-cancellous bone, and which provide a hard, relatively smooth surface. The end 40 of lock 24 is preferably supplied in a plurality of different sizes and shapes other than the square shaped end 40 shown in the figures so as to allow the surgeon to select an appropriately sized and shaped lock which provides a close fit with the space between vertebral bodies.

If necessary, a small amount of a physiologically compatible adhesive of a type known in the art is applied over the cancellous bone chips just medial to the implant to close off the remaining portion of the opening into the disk space. The patient should be able to ambulate soon after the LIDS procedure because of the stability imparted to the spinal column by the implant of the present invention. Before narrowing of the disk space occurs, the cancellous bone chips will have started the fusion process.

The stabilizer 10 is also used to advantage to perform, for instance, a posterior lateral intertransverse fusion. The implant 22 is inserted into the region of the disk space from which a portion of the disk has been removed as described above with the lock 24 and the posterior lateral fusion performed. Because the implant 22 provides stability to the spine until the posterior lateral fusion is solid, the patient is generally able to ambulate soon after surgery. This procedure also prevents the narrowing of the disk space, which is a common problem with posterior lateral fusion.

Removal of the implant 22 is accomplished with relative ease compared to conventional implants. The bolt 26 is screwed back out of implant 22 and lock 24 is pulled out of the disk space. Applicator 52 is re-inserted and screwed into the bore 30 in implant 22 and used to rotate implant 22 by approximately 90°, causing the first and second sides, having minimal height, to contact the bodies 12 and 14 of adjacent vertebrae 16 and 18 so as to allow posteriorly-directed movement of the implant 22 out of the disk space.

An alternative embodiment of the implant of the present invention is shown in Fig. 4 in which the first and second sides 32' of implant 22' are substantially flat but not parallel along their longitudinal axes. The resulting wedge shape of the implant 22' facilitates insertion into the disk space, the rounded end 36 reducing the likelihood of injury to the nerves of the spinal cord during insertion into the disk space. Likewise, comparison of the widths W', W", and W"' of implant 22' will show that the width W' of implant 22' at the end 36' is less than the width W"' at the end 25'. Both widths are less than the width W" in the middle, expanded portion of implant 22'. In another alternative embodiment (not shown) which provides additional resistance to forward or backward movement of implant 22 in the disk space. the teeth 38 located closest to the end 25 of implant 22 (e.g., the teeth in the distal portion of implant 22) are slanted toward the end 25 and the teeth 38 closest to the end 36 of implant 22 are slanted toward the end 36. The teeth in the middle portion of implant 22, e.g., between the two sets of slanted teeth, are oriented vertically.

Referring now to Figs. 5-13, there is shown an apparatus for aligning adjacent vertebrae constructed in accordance with the teachings of the present invention. The apparatus. indicated generally at reference numeral 110, is comprised of an elongate handle 111 and an elongate body 112. The body 112 is comprised of first and second side-by-side members 113 and 114, respectively, the first member 113 being integrally mounted to handle 111 and the second member 114 being movable relative

to the first member 113 in the direction of the longitudinal axis of the shaft 115 of handle 111. Means, in the form of the teeth 138, is provided on body 112 for selectively engaging the adjacent vertebrae 133, 137 when the body 112 is inserted therebetween to prevent relative movement between the respective first and second members 113 and 114 and the adjacent vertebrae 137 and 133 to which the first and second members 113 and 114 are engaged.

The shaft 115 of handle 111 is provided with a longitudinal bore 116 therethrough having a mandrel 117 positioned therein, the second member 114 being mounted to mandrel 117. At the end opposite first member 113, the shaft 115 is provided with a tubular barrel 118 having a collar 119 positioned therein. Collar 119 is also provided with a longitudinal bore 116', the longitudinal axis of which is aligned with the longitudinal axis of the bore 116 in mandrel 117 which is provided with a set of threads 120 for receiving the threaded end 121 of mandrel 117. Collar 119 is retained within barrel 118 by the keeper 122 which is retained on the end of barrel 118 by screws 123. An adjustment knob 124 is integrally mounted to collar 118 by screws 126. As a result of this construction, when mandrel 117 is rotated by turning adjustment knob 124, the second member 114 moves relative to first member 113 from a first position in which the members 113 and 114 are in side-by-side, parallel relationship to each other to a second position along the longitudinal axis of the shaft 115 of handle 111 in which the two members remain parallel to each other but are no longer side-by-side as shown in Fig. 11. Referring to Figs. 7-10, it can be seen that one surface of first member 113 is formed in the shape of a half round hollow 127 for receiving the round mandrel 117 for retaining the two members 113 and 114 in tight, parallel. side-by-side relationship when second member 114 is moved from the first position to the second position.

When the first and second members 113 and 14 are in the first side-by-side position shown in Figs. 5 and 6, e.g., when the mandrel 117 is rotated to draw the end 136 of second member 114 against the end 154 of handle 111, the two members 113 and 114 form an elongate body 112 having a shape which is similar to the shape of the monolithic implant 22 shown in Figs. 1-4. Referring, however, to the body 112 for the time being, when side-by-side, the two members 113 and 114 form a body 112 that is comprised of first and second sides 132 and third and fourth sides 134 providing a substantially rectangularly-shaped cross-section. The height H_6 of the rectangularly-shaped cross-section is defined by first and second sides 132 and the width W_6 is defined by the third and fourth sides 134 and, as is apparent by

comparison of H_6 and W_6, the height H_6 of body 112 is less than the width W_6. As will be explained below, H_6 is minimized to facilitate insertion of the second end 136 into, and positioning of body 112 in, the disk space from which a portion of the intervertebral disk 130 was removed and W_6 is maximized to provide the desired stabilization to adjacent vertebrae 133 and 137. Third and fourth sides 134 are arched from one end of body 112 to the other to provide the portion of body 112 intermediate the ends 125 and 136 with a width W'_6 which is larger than the width W''_6 at the ends 125 and 136. Because the sides 132 of body 112 are substantially flat and the sides 134 are arched from one end 125 to the other end 136, body 112 is described as being a biplanar, bi-convex body. The convex, or arched, sides 134 of body 112 are provided with a plurality of teeth 138 for biting into the adjacent vertebrae 133 and 137 as will be explained in more detail below. The end 136 of body 112 is formed in a blunt, or rounded shape to reduce the likelihood of injury to the nerves of the spinal cord during insertion into the disk space.

Referring now to Fig. 11, the use of the apparatus 110 for reduction of spondylolisthesis is shown. In Fig. 11, the fourth lumbar vertebrae (L4) 133 is shown as having shifted anteriorally, leaving that vertebrae out of alignment with the fifth lumbar vertebrae (L5) 137 and the vertebrae comprising the sacrum 135. To correct this misalignment, surgery is performed as in a simple diskectomy and the intervertebral disk (not shown) is exposed through a small laminotomy. Disk material is removed and any nerve root compression is corrected. The posterior longitudinal ligament (not shown) and disk cartilage are removed until the surface of the bodies 129 and 131 of the adjacent vertebrae (L4 and L5) 133 and 137, respectively, are exposed above and below the disk space.

Using spreaders such as those disclosed in International Application No. PCT/US95/00347, the adjacent vertebrae 133 and 137 are distracted to open the disk space. The body 112 of apparatus 110, having the first and second members 113 and 114 initially in the above-described side-by-side relationship, is then inserted into the disk space with the top and bottom thereof, i.e., the first and second substantially planar sides 132, engaging the adjacent vertebrae 133 and 137 so that the teeth 138 formed on the third and fourth sides 134 of body 112 extend into the disk space without engaging the adjacent vertebrae 133 and 137. The implant is oriented in the disk space so that, when rotated as described below, the first member 113 is the portion of the body 112 which contacts the body 131 of L5 137 and the second member contacts the body 129 of L4 133. In other words, body 112 is oriented so

that first member 113 is positioned in close proximity to the body 131 of the vertebrae 137 which is aligned with the axis, or centerline CL, of the spinal column and second member 114 is positioned in close proximity to the axis of the body 129 of the vertebrae 133 which is out of alignment. The body 112 of apparatus 110 is inserted until the middle portion of first member 113 is positioned adjacent the concavity in the upper surface of the body 131 of the L5 137. Using the adjustment knob 124, mandrel 117 is then rotated to advance the second member 114, e.g., the portion having the wider width W''_6, anteriorally until the middle portion, e.g., the portion having the wider width W''_6, of second member 114 is positioned adjacent the concavity of the lower surface of the body 129 of L4 133. As noted above, the wider middle portion W''_6 of each of the members 113 and 114 comprising the body 112 of apparatus 110 provides maximal engagement of the concave shaped surface of the body of the vertebrae when the body 112 is rotated by approximately 90° as described below. Depending upon the circumstances of each surgery, it may also be advantageous to "pre-adjust" the body 112 by advancing the second member 114 to the second position by the amount of the misalignment before inserting the body 112 of apparatus 110 into the disk space. The amount of slippage of L4 133 relative to L5 137 is calculated using known methods and/or estimated from X-ray films or other images.

Once the first and second members 113 and 114 are approximately aligned with each of the adjacent vertebrae 133 and 137 by positioning the wide, middle portion of each member in the respective concavities of the vertebrae, using the barrel 118 of handle 111, the body 112 of apparatus 110 is rotated by approximately 90° to cause the teeth 138 formed on the surfaces 134 of first and second members 113 and 114 to engage the bodies 129 and 131 of the respective adjacent vertebrae 133 and 137 as shown in Fig. 11. Using the adjustment knob 124, mandrel 117 is then rotated in the opposite direction to draw second member 114 back into the first, side-by-side, parallel relationship with first member 113, pulling the vertebrae to which it is engaged, i.e., L4 133, back into alignment with L5 137.

The diskectomy and laminotomy are preferably performed bilaterally. In other words, the above-described surgical procedure is performed to the side of the center line of the adjacent vertebrae such that the portion of the intervertebral disk which is removed is "off center" relative to the bodies 129 and 131 of the respective adjacent vertebrae 133 and 137. An identical surgery is performed on the other, or second, side of the center line of the adjacent vertebrae and the body 112 of a second

apparatus 110 (not shown in the figures for purposes of clarity) is inserted into the disk space after that second procedure. The adjacent vertebrae 133 and 137 are then aligned by rotation of the respective adjustment knobs 124 of both apparatus 110 until the vertebrae are aligned. In this fashion, the body 112 of one of the two apparatus 110 retains the adjacent vertebrae in alignment even after removal of the other implant.

Removal of the body 112 is accomplished by rotation by approximately 90° (preferably in the direction opposite the direction of rotation which was utilized to cause the teeth 138 to engage the respective adjacent vertebrae 133 and 137) so as to disengage the teeth 138 from L4†133 and L5 137. While the body of the second apparatus remains in the disk space on the second side of the center line, an implant such as the implant 22 (see Figs. 1-4) is inserted into the disk space from which the body 112 was removed on the end of applicator 52 with the flat surfaces 32 adjacent the bodies 129 and 131 of adjacent vertebrae 133 and 137 and moved in an anterior-posterior direction so as to enable the implant 22 to be positioned in the disk space at a position in which the expanded, middle portion and the smaller width ends 25 and 36 of the third and fourth sides 34 of implant 22 contact the respective lower and upper surfaces of the bodies 129 and 131 of the adjacent vertebrae 133 and 137 when rotated by approximately 90° using the applicator.

After rotation, the applicator 52 is detached from the implant 22 by unscrewing and backed out of the incision. Lock 24 is then inserted through that same incision and, using the slot 46 and key 48, the bore 28 in lock 24 and bore 30 in implant 22 are aligned and the bolt 26 is inserted and tightened to secure lock 24 to the implant 22 all as previously described. Once the monolithic implant 22 is locked in place on the first side of the center line of the adjacent vertebrae 133 and 137, the body 12 of the second apparatus 10 on the second side of the center line, which has remained in place throughout the procedure, is then removed. The disk space is then packed with cancellous bone chips through this second side and a second monolithic implant 22 (also not shown) is inserted, positioned, rotated, and locked in its place in the same manner as described above. If necessary, a small amount of a physiologically compatible adhesive of a type known in the art is applied over the cancellous bone chips just medial to the implants to close off the remaining portion of the openings into the disk space.

Referring now to Figs. 12 and 13, there is shown an alternative embodiment of the spondylolisthesis reduction apparatus, indicated generally at reference numeral

110a, of the present invention. Where possible, the component parts of apparatus 110a are labelled with the reference numeral (and the "a" designation) of the corresponding parts of the apparatus 110. Apparatus 110a is comprised of a handle 111a and body 112a, the body 112a being comprised of first (fixed) and second (movable) members 113a and 114a, respectively. The second member 114a is mounted to a mandrel 117a positioned in a longitudinal bore 116a in the shaft 115a by a swivel joint 140a and moves relative to first member 113a by action of the threads 121a formed on the outside surface of mandrel 117a on the threads 120a formed on the shaft 115a of handle 111a. The body 112a of apparatus 110a is shaped in the same substantially rectangular cross-sectional shape as the body 112 of apparatus 110 and the component parts of apparatus 110a function in the same manner as the parts of apparatus 110.

Apparatus 110a also includes a plurality of fine serrations 142a formed on the opposed surfaces 144a and 146a of first and second members 113a and 114a, respectively. The serrations 142a act to resist longitudinal movement of second member 114a relative to first member 113a.

WHAT IS CLAIMED IS:

1. A vertebral disk stabilizer comprising:

an elongate implant (22) having first, second, third, and fourth sides (32. 34) providing said implant with a substantially rectangular cross-sectional shape of minimal height (H) defined by the first and second sides and maximal width (W) defined by the third and fourth sides, the third and fourth sides being arched from one end of said implant to the other end of said implant to provide the middle portion of said implant with a width larger than the width of the ends of said implant;

a lock (24) having a bearing surface (50) formed thereon, and

means (26, 28, 30) for detachably mounting said lock to one end of said implant to prevent rotation of said lock relative to said implant.

2. The stabilizer of claim 1 wherein the third and fourth sides of said implant are provided with teeth (38).

3. The stabilizer of claim 1 wherein said lock is provided with a substantially flat surface (42) for contacting either the first or the second side of said implant to prevent rotation of said lock relative to said implant.

4. The stabilizer of claim 1 wherein the corners (35) of said implant between the first, second, third, and fourth sides are rounded.

5. The stabilizer of claim 1 wherein the end (36) of said implant opposite the end to which said lock is mounted is rounded.

6. The apparatus of claim 1 wherein said bearing surface (50) is oriented at an angle of approximately 90° to the first and second sides of said implant when secured thereto.

7. The stabilizer of any of claims 1-6 additionally comprising an applicator (52) for detachably mounting to said implant (22).

8. Apparatus for insertion between and alignment of adjacent vertebrae comprising:

a body (112) formed of first and second side-by-side elongate members (113, 114);

an elongate handle (111) having said first member mounted thereto;

an elongate mandrel (117) having said second member mounted thereto and movable relative to and along the longitudinal axis of said handle for moving said first member relative to said second member along the longitudinal axis thereof; and

a plurality of teeth (138) formed on said body for engaging adjacent vertebrae (133, 137) when said body is inserted therebetween using said handle.

9. The apparatus of claim 8 wherein said body is substantially rectangularly-shaped in cross-section, the sides (132) of said rectangularly-shaped body forming the width (W_6) of said body having a dimension larger than the sides (134) of said body forming the height (H_6) of said body.

10. The apparatus of claim 8 wherein said teeth are formed on the sides (134) of said body forming the height of said body.

11. The apparatus of claim 8 wherein the width of said body is smaller at the ends (125, 136) of said body than in the middle of said body.

12. The apparatus of claim 11 wherein the teeth are formed on the sides of said body forming the height of said body and in the portion of said body forming the middle of said body.

13. The apparatus of claim 8 wherein said handle is provided with a longitudinal bore (116) and said mandrel is positioned therein.

14. The apparatus of claim 8 wherein said second member is provided with a rounded surface (127) for receiving a complementary-shaped surface on said first member for maintaining said first and second members in side-by-side alignment during movement of said first member relative to said second member.

15. Apparatus for aligning adjacent vertebrae comprising:

an elongate handle (111) having a longitudinal bore (116) therethrough;

a mandrel (117) positioned in the bore in said handle and movable therein;

a body (112) comprised of first and second side-by-side members (113. 114), the first member being mounted to the end of said handle and the second member being mounted to the end of said mandrel; and

means (138) formed on said body for selectively engaging adjacent vertebrae when said body is inserted therebetween to prevent relative movement between the respective first and second members (113, 114) and the respective adjacent vertebrae (133, 137) to which the first and second members are engaged.

16. The apparatus of claim 15 wherein said body is formed in substantially rectangularly-shaped cross-section, said vertebrae engaging means being formed on opposite sides (134) thereof.

17. The apparatus of claim 16 wherein the height (H_6) of said rectangularly-shaped body is less than the width (W_6) of said body.

18. The apparatus of claim 16 wherein the sides (134) of said rectangularly-shaped body defining the height of said body are arched from the first end of said body to the second end of said body to provide said body with a width in the portion intermediate the ends thereof which is larger than the width at the ends of said body.

19. The apparatus of claim 15 wherein said vertebrae engaging means comprises teeth (138) formed on the surface of said body.

20. The apparatus of claim 15 wherein the side of said second member abutting said first member when said first and second members are side-by-side is provided with a half round hollow (127) for retaining said first and second members in tight. parallel, side-by-side relationship.

21. A method of stabilizing two adjacent vertebrae (16, 18) after removal of a portion of the intervertebral disk to form a disk space therebetween comprising the steps of:

inserting a substantially rectangular, elongate implant (22) having a width (W) greater than the height (H) of the implant into the disk space with the implant oriented so that the top and bottom (32) thereof engage the bodies (12. 14) of the adjacent vertebrae;

rotating the implant approximately 90° in the disk space to contact the bodies of the adjacent vertebrae with the sides (34) of the implant; and

securing a lock (24) to the implant to prevent rotation of the implant relative to the lock, the lock having a surface (50) for bearing against the body of the adjacent vertebrae to prevent rotation of the lock relative to the body of the adjacent vertebrae against which the surface of the lock bears.

22. The method of claim 21 additionally comprising mounting an applicator (52) to one end (25) of the implant before inserting the implant into the disk space.

23. The method of claim 22 wherein the implant is rotated by rotating the applicator.

24. The method of claim 23 additionally comprising detaching the applicator from the implant before securing the lock to the implant.

25. The method of any of claims 21-24 additionally comprising preventing movement of the implant in the disk space along the axis of rotation of the implant.

26. A method of aligning adjacent vertebrae (133, 137) after removing a portion of the intervertebral disk from therebetween to form a disk space comprising the steps of:

inserting an elongate body (112) having means (138) formed on opposite sides (134) thereof for selectively engaging the vertebrae adjacent the disk space into the disk space, the body being comprised of first and second side-by-side members (113, 114), with the engaging means extending into the disk space without engaging the adjacent vertebrae;

moving the second member relative to the first member until the first and second members are approximately aligned with each of the adjacent vertebrae;

rotating the elongate body approximately 90° to cause the vertebrae engaging means thereon to engage the vertebrae; and

moving the second member relative to the first member to align the vertebrae to which each member is engaged.

27. The method of claim 26 wherein the first and second members are moved by moving a mandrel (117) to which the second member is mounted.

28. The method of claim 26 wherein the body is elongate and wider in the middle portion than at the ends (125, 136) thereof and the first and second members are aligned with the adjacent vertebrae by positioning at the point relative to the adjacent vertebrae at which the respective wider middle portions maximally engage the respective adjacent vertebrae.

29. The method of claim 26 wherein the body is inserted into the disk space on one side of the centerline of the adjacent vertebrae.

30. The method of claim 29 additionally comprising inserting a second body on a second side of the centerline of the adjacent vertebrae.

31. The method of claim 30 additionally comprising replacing the first body with a monolithic body (22) after aligning the adjacent vertebrae.

32. The method of claim 31 additionally comprising replacing the second body with a monolithic body.

33. The method of claim 26 additionally comprising removing the elongate body from the disk space and inserting a substantially rectangular, elongate implant (22) having a width (W) greater than the height (H) of the implant into the disk space with the implant oriented so that the top and bottom (32) thereof engage the vertebrae, rotating the implant, and securing a lock (24) to the implant to prevent further rotation of the implant.

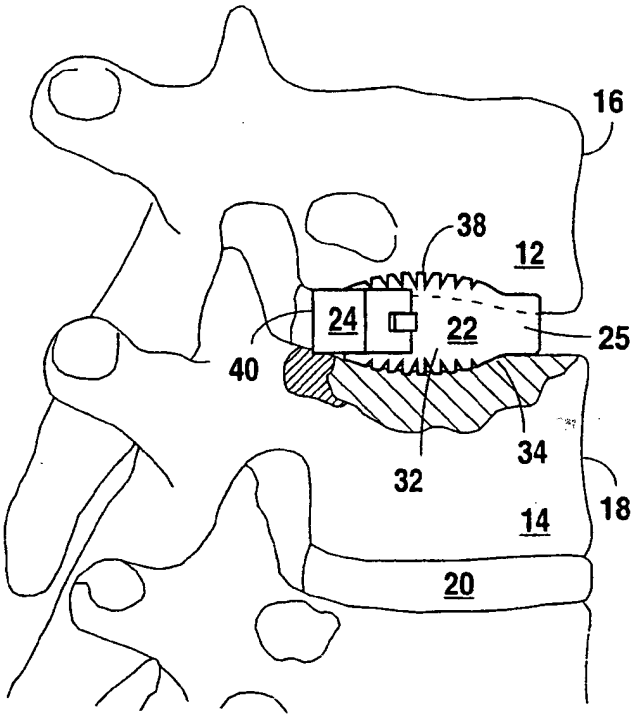

16
38
12
24
22
25
40
34
32
18
14
20

Fig. 1

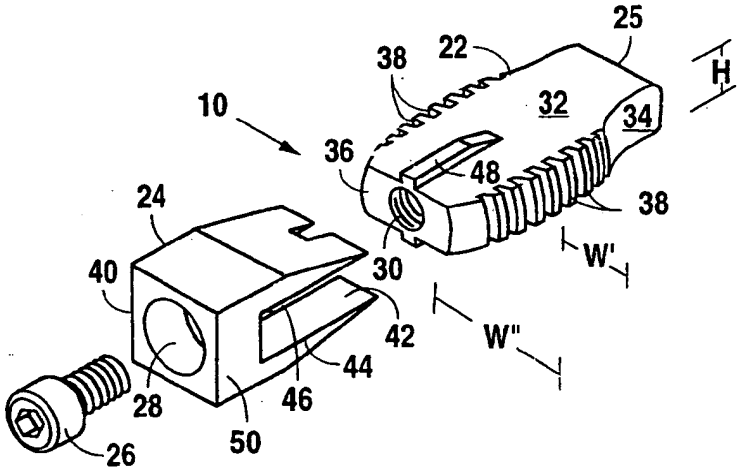

25
22
38
H
10
32
34
36
48
24
38
40
30
W'
42
W"
44
46
28
50
26

Fig. 2

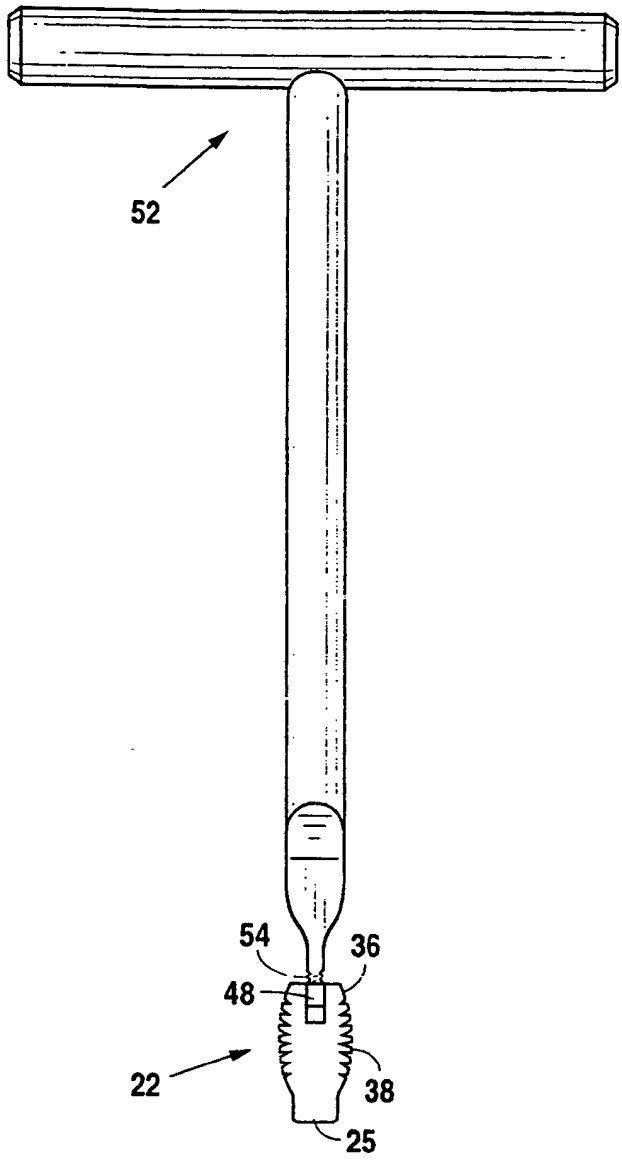


Fig. 3

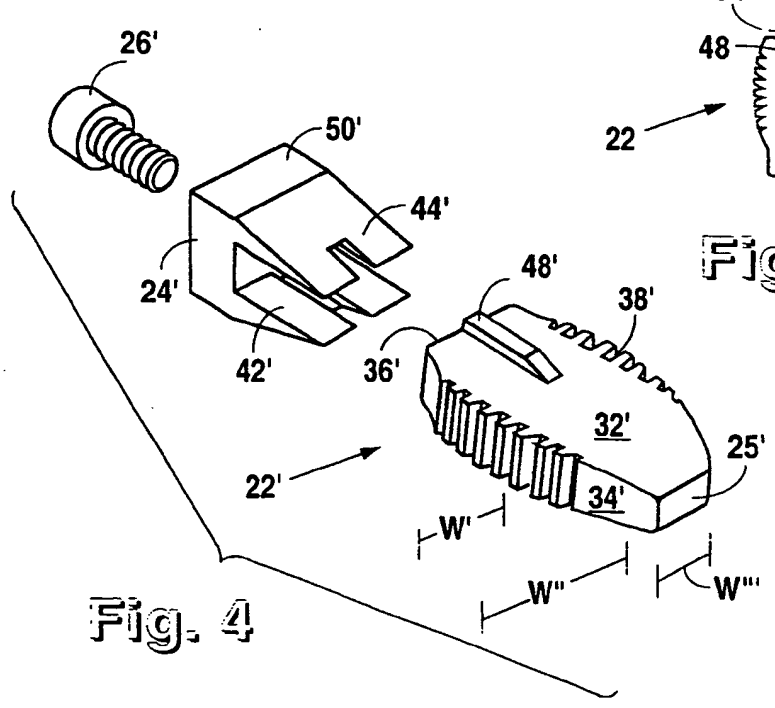


Fig. 4

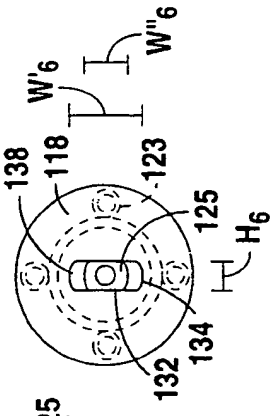


Fig. 6

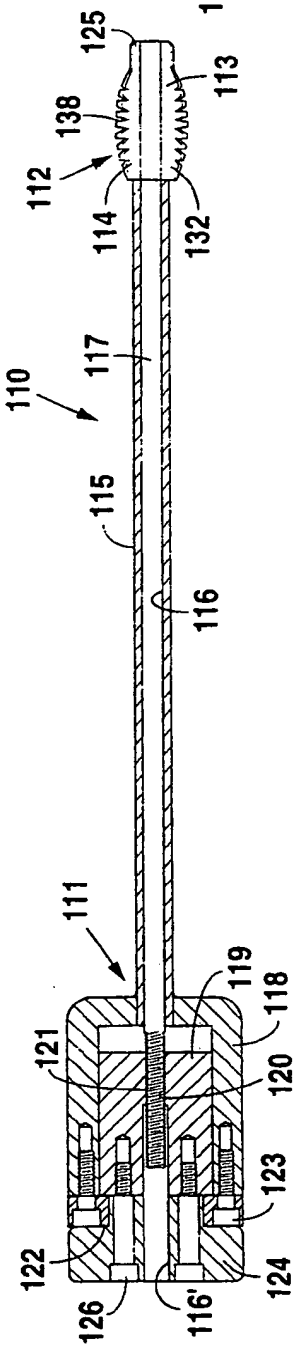


Fig. 5

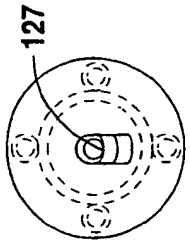


Fig. 8

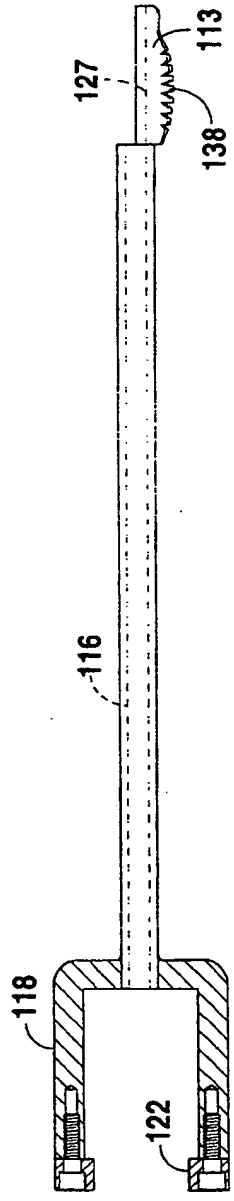


Fig. 7

Fig. 10

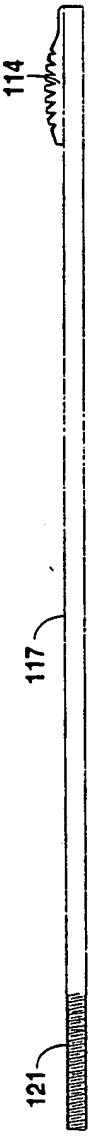


Fig. 9

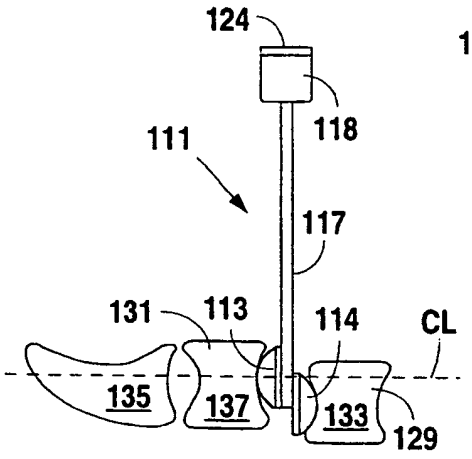


Fig. 11

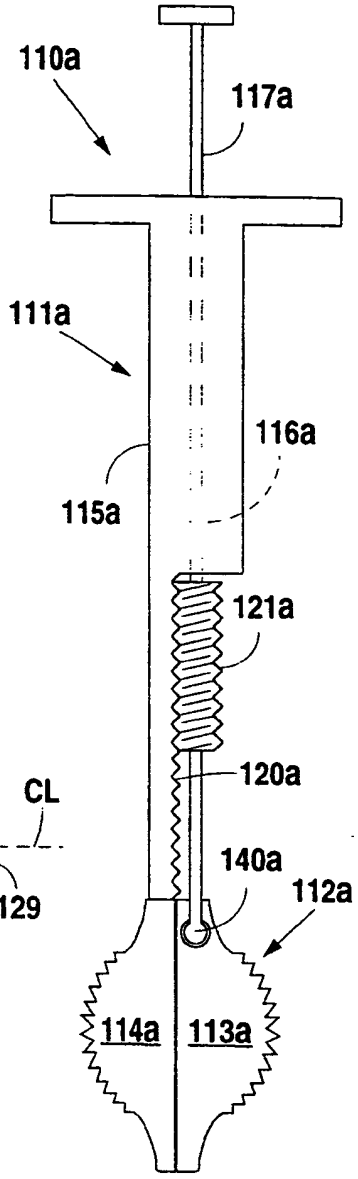


Fig. 12

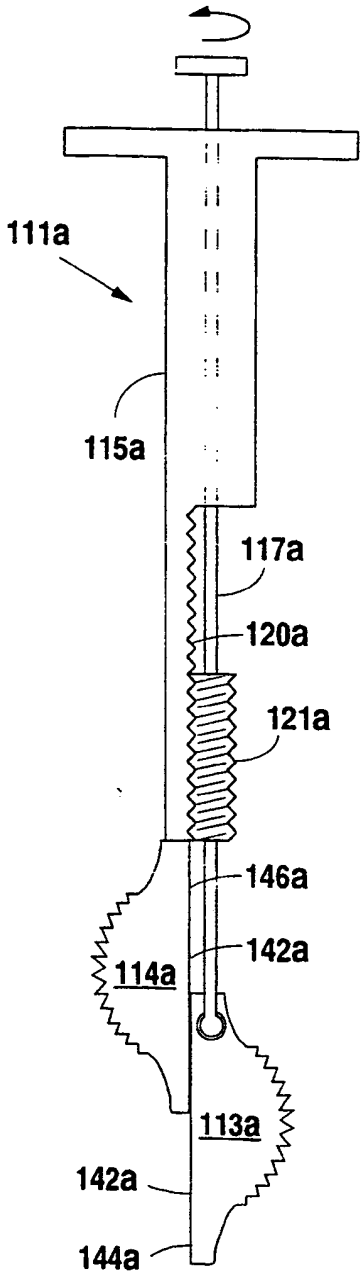


Fig. 13

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44, 2/46, A61B 17/58, 17/02 — A3

(11) International Publication Number: **WO 96/40016**

(43) International Publication Date: 19 December 1996 (19.12.96)

(21) International Application Number: PCT/US96/09114

(22) International Filing Date: 6 June 1996 (06.06.96)

(30) Priority Data:
08/475,211 7 June 1995 (07.06.95) US
08/482,974 7 June 1995 (07.06.95) US

(71)(72) Applicant and Inventor: PISHARODI, Madhavan [US/US]; 942 Wild Rose Lane, Brownsville, TX 78520 (US).

(74) Agent: WISNER, Mark, R.; Sroufe, Payne & Lundeen, L.L.P., Suite 1230, 1700 West Loop South, Houston, TX 77027-3008 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

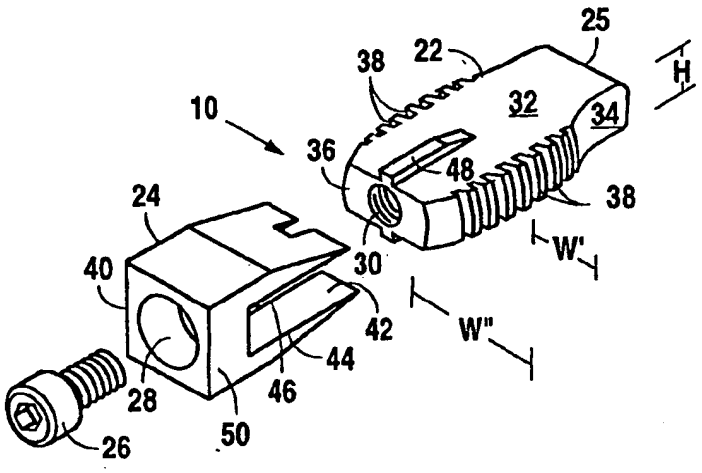
Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
13 February 1997 (13.02.97)

(54) Title: INTERVERTEBRAL DISK STABILIZER AND INSTRUMENT FOR REDUCTION OF SPONDYLOLISTHESIS

(57) Abstract

A middle expanded, removable disk implant (22) with substantially rectangular cross-sectional shape with a minimal height (H) and a width (W) greater than the height which is detachably mounted to an applicator (52) for insertion into the anatomical region between two adjacent vertebrae (16, 18) from which a portion of the intervertebral disk has been removed. The implant is positioned by anterior-posterior movement in the disk space to the position in which both the expanded middle portion and the smaller diameter end (25, 36) portions of the implant engage the bodies (12, 14) of the adjacent vertebrae and then rotated to bring the sides (34) of the implant defining the height of the implant into engagement with the bodies of the adjacent vertebrae. A lock (24) is then secured to the implant to prevent further rotation thereof. In the event the adjacent vertebrae need to be aligned before fusion, an elongate implant (112) is provided which is split longitudinally into side-by-side members (113, 114) movable relative to each other and which is inserted into the disk space between two misaligned vertebrae (133, 137). The members are provided with teeth (138) for engaging the adjacent vertebrae and the implant formed by the two side-by-side members is rectangularly-shaped in cross section, the height (H_6) of the rectangularly-shaped cross section being less than the width (W_6) so that the implant can be inserted between the adjacent vertebrae with the lesser, height dimension oriented in the same direction as the axis of the spinal column and the larger width dimension at approximately a right angle to that axis. One member is then moved relative to the other from the first side-by-side position along the longitudinal axis of the implant to a second position in which the members are aligned with the respective, adjacent, misaligned vertebrae and the implant is rotated 90° to engage the teeth to the bodies of the adjacent vertebrae. The two members are then brought back into the first side-by-side position to draw the vertebrae into alignment and the implant is rotated approximately 90° to disengage the teeth from the vertebrae for removal from the disk space.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

INTERNATIONAL SEARCH REPORT

Inter ional Application No
PCT/US 96/09114

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44 A61F2/46 A61B17/58 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 08306 A (SYNTHES AG) 30 March 1995 see claims 1,3,8-10,32; figures 7-9,17	1-3,7
A	see figures 10,11	4

Y,P	WO 95 26164 A (MICHELSON) 5 October 1995 see abstract; figures 1-9	1-3,7

A	WO 92 14423 A (MADHAVAN) 3 September 1992 see abstract; figures 8,9	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Date of the actual completion of the international search
8 October 1996

Date of mailing of the international search report
07. 01. 97

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer
VILLENEUVE, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 96/09114

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-33
because they relate to subject matter not required to be searched by this Authority, namely:
Relate to a surgical method.
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims : 1-7
A vertebral disk stabilizer
2. Claims : 8-14,15-20
Apparatus for insertion between and alignment of adjacent vertebrae.

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 96/09114

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9508306	30-03-95	BE-A-	1007549	01-08-95
		CA-A-	2151481	30-03-95
		EP-A-	0670702	13-09-95
		JP-T-	8503876	30-04-96
WO-A-9526164	05-10-95	AU-A-	2129095	17-10-95
WO-A-9214423	03-09-92	US-A-	5171278	15-12-92
		AU-A-	1454192	15-09-92
		CA-A-	2104391	23-08-92
		DE-D-	69209494	02-05-96
		DE-T-	69209494	31-10-96
		EP-A-	0571555	01-12-93
		JP-T-	6504704	02-06-94
		US-A-	5390683	21-02-95